

REMARKS

Claims 1-37 are pending in the application. Favorable reconsideration in light of the amendments, the new claims, and the remarks which follow is respectfully requested.

The Obviousness Rejection

Claims 24, 25, and 35 have been rejected under 35 U.S.C. § 103(a) over Saulle in view of Lowe et al. Saulle et al relates to mitochondrial genes encoding ATPase8. Specifically, Saulle et al merely teaches a nucleic acid sequence of a region encoding ATPase8. However, this region is relatively variable between animal species. Saulle et al further teaches that a relatively conserved portion is present within the region encoding ATPase8. Lowe et al merely discloses a computer program for rapid selection of preferable primers for polymerase chain reaction to amplify a target sequence effectively. The Examiner contends that one skilled in the art would have used the software of Lowe et al on the genes of Saulle et al to generate primers, and thus render the invention obvious.

In order to identify a primer to detect DNA derived from a ruminant, it is required that the primer has (i) a specific portion of the entire genome sequence, (ii) a specific length of the sequence, and (iii) a specific combination of these sequences. Saulle et al does not teach or suggest that the ruminant deer sequence can satisfy the three above mentioned requirements for the primer. And in order to run the computer program as disclosed by Lowe et al, one skilled in the art must have selected a specific region (i.e. target sequence) amplified by a specific primer pair for detection of ruminant DNA. Consequently, even though Saulle et al discloses the complete nucleic acid sequence to be detected, one skilled in the art would NOT have selected (i) a specific portion of the entire genome sequence, (ii) a specific length of the sequence, and further (iii) a specific combination of these sequences.

As long as the target sequence to be amplified cannot be selected appropriately, even if the known nucleic acid sequence of Saulle et al is combined with the step of generating and designing primers as taught by Lowe et al, the specific combination of primers of the claimed invention could not be obtained by those skilled in the art. In other words, one skilled in the art would not have expected to generate functional primers without extensive experimentation to determine which primers actually perform as desired in PCR. This is because Saulle et al does NOT teach or suggest whether or not the ruminant DNA can be actually detected without detecting DNAs other than the ruminant DNA.

Furthermore, one skilled in the art would not have been able to generate the claimed primers using the software of Lowe et al in combination of the sequence disclosed by Saulle et al for these additional reasons.

Saulle et al does NOT teach or suggest primers that discriminate between homologous ATPase8 targets. The software of Lowe et al generates possible primers from a single user inputted target DNA sequence by optimizing GC content, GC bases present at the 3' end, length of amplification product, contiguous base pair homology, and annealing temperature of possible primers. Therefore, while one skilled in the art might conceivably expect Saulle et al to be useful in generating primers capable of amplifying an ATPase8 target, none of the optimization steps of Lowe et al indicates that such primers can discriminate between two homologous ATPase8 targets.

In order to have a reasonable expectation of designing primers that can discriminate between two homologous APTase9 targets, it is necessary to compare the desired DNA target or targets with homologous undesired target or targets. For example, Fig. 5 shows the ability of the anicon5 and anicon3 primer pair to detect mammalian DNA targets including non-ruminants pig, horse, rabbit and whale. Fig. 6 shows the ability of the rumicon5 and rumicon3 primer pair to detect ruminant DNA targets while distinguishing non-ruminants pig, horse, rabbit and whale. The software of Lowe et al does not have the functionality to design a primer with the discrimination

of the rumicon5 and rumicon3 primer pair for at least the reason that designing such primers requires comparing several DNA sequences.

Therefore, it would NOT have been obvious to a person of ordinary skill in the art to combine the known nucleic acid sequence as taught by Saulle et al with a step of generating primers and designing primers as taught by Lowe et al to amplify and increase the primer specificity and to detect a ruminant-specific DNA. Withdrawal of the rejection is respectfully requested.

Although the combination of Saulle et al and Lowe et al is not conceded, even if the two were combined, numerous to infinite numbers of primer pair combinations can be theoretically made. In this situation, it would require undue experimentation to select which primer pair is specific for a ruminant DNA among the numerous to infinite numbers of primer pair combinations; that is, which primer pair can in fact distinguish between ruminant DNA from non-ruminant DNA. This is, in part, because Saulle et al does not teach or suggest whether or not any region encoding ATPase8 can be used as a target sequence to distinguish an animal species from other animal species, for example, not only a classification of the Family level but also the Order level.

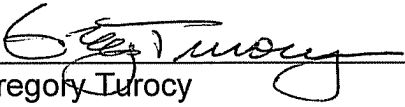
It is simply not possible for the computer program of Lowe et al to design a specific primer pair that can be used to specifically distinguish a mammal DNA from other animal DNA and that can further specifically distinguish a ruminant DNA from the mammal DNA. Such a highly distinguishable primer pair cannot be designed by running the computer program of Lowe et al because the design for specifically distinguishing a ruminant DNA from the mammal DNA does not set up in the computer program of Lowe et al. Withdrawal of the rejection is respectfully requested for this additional reason.

Should the Examiner believe that a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact Applicants' undersigned attorney at the telephone number listed below.

In the event any fees are due in connection with the filing of this document, the Commissioner is authorized to charge those fees to our Deposit Account No. 50-1063.

Respectfully submitted,

**AMIN, TUROCY & CALVIN, LLP**

  
\_\_\_\_\_  
Gregory Turocy  
Reg. No. 36,952

24<sup>th</sup> Floor  
1900 East 9<sup>th</sup> Street  
Cleveland, Ohio 44114  
(216) 696-8730  
Fax (216) 696-8731